

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

THIS DOCUMENT RELATES TO:)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
v.)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

9070

Bartle, J.

May 11 , 2013

Michelle L. Stanford ("Ms. Stanford" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Seth A. Stanford, Ms. Stanford's child, also submitted a derivative claim for benefits. The Show Cause Record reflects that the Trust determined claimant's child was not entitled to derivative benefits as a matter of state law. As claimant did not contest this determination of the Trust, the court need not address this issue.

support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In May, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Ramdas G. Pai, M.D., F.A.C.C., F.R.C.P. Based on an echocardiogram dated October 25, 2002, Dr. Pai attested in Part II of Ms. Stanford's Green Form that she suffered from severe mitral regurgitation and

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

had ACC/AHA Class I indications for surgery to repair or replace the aortic and/or mitral valve(s) where such surgery was not performed because the valvular repair/replacement surgery was medically contraindicated.⁴ Based on such findings, claimant would be entitled to Matrix A-1, Level III⁵ benefits in the amount of \$937,145.⁶

In claimant's Green Form, Dr. Pai also attested that claimant did not have a rheumatic mitral valve. Under the Settlement Agreement, the presence of a rheumatic mitral valve requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)e). Evidence of a rheumatic mitral valve is defined by the Settlement Agreement as "doming of the anterior leaflet and/or anterior motion of the posterior leaflet and/or commissural fusion." See id. As the Trust does not

4. Dr. Pai also attested that claimant suffered from pulmonary hypertension secondary to moderate or greater mitral regurgitation, an abnormal left ventricular end-systolic dimension, and New York Heart Association Functional Class IV symptoms. These conditions are not at issue in this claim.

5. In her Green Form, Ms. Stanford requested Matrix Benefits at Level IV. Upon review of claimant's Green Form and supporting materials, the Trust determined, and claimant does not contest, that Ms. Stanford only alleged conditions consistent with a claim for Level III benefits.

6. Under the Settlement Agreement, a claimant is entitled to Level III benefits if the claimant had: "Severe regurgitation and the presence of ACC/AHA Class I indications for surgery to repair or replace the aortic and/or mitral valve(s) and a statement from the attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist supported by medical records regarding the recommendations made to the patient concerning valvular surgery, with the reason why the surgery is not being performed." Settlement Agreement § IV.B.2.c.(3)(b).

contest claimant's entitlement to Level III benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

In May, 2005, the Trust forwarded the claim for review by Ernest C. Madu, M.D., F.A.C.C., F.E.S.C., one of its auditing cardiologists.⁷ In audit, Dr. Madu concluded that there was no reasonable medical basis for Dr. Pai's finding that claimant did not have a rheumatic mitral valve. Specifically, Dr. Madu explained:

Echocardiogram of 10/25/2002 shows doming of the anterior leaflet. Additionally pathology report of resected mitral valve confirms "Commissural fusion" and states ... "the valvular findings are typical for a post rheumatic process...."

Based on Dr. Madu's finding that claimant had a rheumatic mitral valve, the Trust issued a post-audit determination that Ms. Stanford was entitled only to Matrix B-1, Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁸ In contest, claimant submitted

7. Pursuant to Pretrial Order ("PTO") No. 3882, all Level III, Level IV and Level V Matrix claims were subject to the Parallel Processing Procedures ("PPP"). As Wyeth did not agree that claimant had a Matrix A-1, Level III claim, the Trust audited Ms. Stanford's claim pursuant to the PPP.

8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit
(continued...)

letters from Dr. Pai and Jacques J. Lamothe, M.D. In his letter, Dr. Pai stated that claimant's "valve disease [is] related to Phen fen use" and that "[b]ecause of the clinical circumstances, it is very unlikely to be rheumatic heart disease." Dr. Lamothe stated, in relevant part, that:

The pathologic findings noted revealed changes which were typical for post rheumatic processes; however, these findings have also been associated with chronic use of Phen-Fen. There is also evidence of a myxomatous mitral valve with commissural fusion which is also associated with Phen-Fen use. There is also no evidence of congenital mitral valve disease.

In my opinion Phen-Fen either caused or had a major impact on the patient's development of mitral valve stenosis and insufficiency which ultimately prompted mitral valve replacement. There is no clinical or historical evidence that the patient had rheumatic heart disease prior to the discovery of her valvular cardiomyopathy even if sub clinical rheumatic heart disease was present.

Claimant also submitted a letter from her parents indicating that she never had rheumatic fever. Claimant argued, therefore, that there was a reasonable medical basis for her attesting physician's finding that she did not have a rheumatic mitral valve. Claimant further contended that the pathology report's comment as to "rheumatic process" was not an exclusive finding.

The Trust then issued a final post-audit determination, again determining that Ms. Stanford was entitled only to Matrix B-1, Level III benefits. Claimant disputed this final

8. (...continued)

Rules contained in PTO No. 2807 apply to Ms. Stanford's claim.

determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Stanford's claim should be paid. On November 20, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6696 (Nov. 20, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on December 21, 2007. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she did not have a rheumatic mitral valve. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, claimant again asserts that she should prevail on her claim because she never had rheumatic fever.⁹ In response, the Trust argues that claimant failed to establish a reasonable medical basis for her claim because claimant did not rebut the auditing cardiologist's finding that the echocardiogram revealed evidence of a rheumatic mitral valve. The Trust also contends that claimant cannot rely on the pathology report to support her claim because the report does not specifically state that there was no evidence of rheumatic valve disease. Finally, the Trust asserts that the statements by claimant, her cardiologists, and her parents that there is no history of claimant having rheumatic fever do not establish a reasonable medical basis for Ms. Stanford's claim.

After reviewing the entire Show Cause Record, we find claimant's arguments without merit. The Settlement Agreement specifically provides that a claimant will receive reduced Matrix Benefits when certain enumerated medical conditions, including a rheumatic mitral valve, are present:

M-Mode and 2-D echocardiographic evidence of rheumatic mitral valves (doming of the anterior leaflet and/or anterior motion of

9. Claimant also asserts that the Trust mishandled her claim "from start to finish," which, according to claimant, "would justify a Breach of Contract for Specific Performance." In support of this argument, claimant challenged the amount of Matrix Benefits determined by the Trust. In its response, the Trust set forth the basis of its calculation of Matrix B-1 benefits previously paid to claimant. We reject claimant's argument. There is no evidence that the Trust improperly determined the amount of Matrix Benefits due claimant or mishandled claimant's claim.

the posterior leaflet and/or commissural fusion), except where a Board-Certified Pathologist has examined mitral valve tissue and determined that there was no evidence of rheumatic valve disease.

Settlement Agreement § IV.B.2.d.(2)(c)ii)e) (emphasis added).

Here, the auditing cardiologist determined, and claimant does not contest, that her echocardiogram revealed evidence of a rheumatic mitral valve. In particular, Dr. Madu observed "doming of the anterior leaflet."

Similarly, the pathology report of claimant's mitral valve states, "The valvular findings are typical for a post rheumatic process." To meet her burden, claimant relies on additional language in the pathology report, which states that "a variety of substances have also been associated with this particular change. Clinical correlation is recommended." Thus, according to claimant, the pathology report does not contain an "exclusive finding" of a rheumatic mitral valve and, therefore, there is a reasonable medical basis for the attesting physician's conclusion that claimant did not have a rheumatic mitral valve. Claimant's attempted reliance on the pathology report, however, is misplaced.

Under the Settlement Agreement, if there is echocardiographic evidence of a rheumatic mitral valve, a claim will be reduced to the B-1 Matrix, except where a Board-Certified Pathologist examines the mitral valve tissue and determines that there is no evidence of rheumatic valve disease. See Settlement Agreement § IV.B.2.d.(2)(c)ii)e). Claimant concedes that the

pathology report contains a "non-exclusive finding." Although claimant asserts that a "non-exclusive finding" supports her claim, the opposite is true. Only upon a specific finding by a Board-Certified Pathologist that the mitral valve tissue does not reveal evidence of rheumatic valve disease may a claimant avoid application of the reduction factor at issue. We previously rejected an argument similar to Ms. Stanford's in PTO No. 7466 (Oct. 10, 2007). There, we rejected a claimant's argument that a "nonspecific finding" in a pathology report supported her assertion that she did not have a rheumatic mitral valve. See generally PTO No. 7466 at 9.

Similarly, Ms. Stanford's attempted reliance on the arguments she made in contest to the Trust's post-audit determination and on letters from her cardiologists and her parents also is misplaced. Nothing in the Settlement Agreement provides that evidence of the reduction factor of a rheumatic mitral valve on a claimant's echocardiogram may be disregarded based on an assertion that the claimant never was diagnosed or treated for rheumatic fever. We also previously have held that a claimant cannot meet his or her burden of proving the absence of rheumatic mitral valve by reference to a statement from his or her parent to the effect that claimant never had rheumatic fever. See, e.g., PTO No. 7466 at 10. As noted above, the only means by which a claimant may rebut echocardiographic evidence of rheumatic mitral valve is the specific determination of a Board-

Certified Pathologist as set forth in the Settlement Agreement.

Claimant has not provided such a determination in this case.

Finally, Ms. Stanford's assertion that she is entitled to Matrix A-1 benefits because her "valve disease [is] related to Phen fen use" and "Phen-fen either caused or had a major impact on the patient's development of mitral valve stenosis and insufficiency which ultimately prompted mitral valve replacement" is erroneous. Causation is not at issue in resolving claims for Matrix Benefits. Rather, claimants are required to show that they meet, or in the case of the presence of reduction factors, do not meet, the objective criteria set forth in the Settlement Agreement. As we previously concluded:

Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which that qualification occurred....

PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted:

... [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97. If claimants are not required to demonstrate causation, the converse is also true, namely, in applying the terms of the Settlement Agreement, the Trust does not need to establish that a reduction factor caused the medical condition at issue. The Settlement Agreement unequivocally requires a mitral

valve claim to be reduced to Matrix B if claimant's echocardiogram reveals evidence of a rheumatic mitral valve and a Board-Certified Pathologist has not provided a contrary determination after examination of the mitral valve tissue. We must apply the Settlement Agreement as written. Accordingly, claimant's assertion that the cause of her mitral valve replacement was the ingestion of Diet Drugs is irrelevant to the issue before the court. As claimant does not contest that her echocardiogram revealed evidence of a rheumatic mitral valve, and a Board-Certified Pathologist has not provided a contrary determination, the Settlement Agreement requires that Ms. Stanford's claim be reduced to Matrix B-1.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she did not have a rheumatic mitral valve. Therefore, we will affirm the Trust's denial of Ms. Stanford's claim for Matrix A-1 benefits.